

### **REMARKS/ARGUMENTS**

This Amendment addresses the issues raised in the Official Action of September 3, 2008, a Final Rejection, and accompanies a Request for Continued Examination. Please see also the concurrently filed Information Disclosure Statement which formally makes of record the documents provided by applicants demonstrating the level of skill in this art and the terminology employed.

#### **Amendment of the Claims**

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to advance examination of this application generally.

Although new claim 20 corresponds to claim 8 at the time of Office Action of September 3, 2008 (claim 8 at O.A.), the compounding amount of the ester oil was increased, and in accordance therewith, the compounding amounts of the ester compound, the surfactant and the oil other than ester oil were amended; and further, compounds falling within the definition of the ester oil are specifically defined. As to the compounding amounts of the ester oil, the ester compound, the surfactant and the oil other than ester oil, support in the specification may be found in page 10, lines 1 to 8, page 6, line 30 to page 7, line 4, page 13, lines 12 to 17, and page 14, lines 19 to 23 of the text. All of the recited ester oils excluding "isooctyl palmitate" were those from previous claim 16, and "isooctyl palmitate" is used in Example 8.

Correlation between claims at the Office Action and new claims is as follows:

Previous Claims	8	9	10	11	12	13
New claims	20	21	-	-	22	23
Previous Claims	14	15	16	17	18	19
New claims	24	25	20	-	26	27

#### **Response to the Claim Rejections Under 35 USC §103(a)**

The following references were cited in respect to unobviousness:

'433 reference: JP10-273433A

'672 reference: EP1044672A

It is said that since claims 8-19 lack patentability over the '433 reference in view of the '672 reference, claims 8-19 are rejected under 35 U.S.C. §103 (a) -- in this connection, although the Examiner omitted claim 16 from the first rejection at the beginning of O.A. (page 2), it was included at the latter part (page 5) of O.A.

The reasons given for these rejections, the Examiner says:

“What is lacking (in reference '433) is the inorganic salt.

The '672 reference teaches oil-in-water cosmetics for application to skin or hair (paragraph 0002). Inorganic salts or amino acids are added to impart stability to W/O emulsion (abstract). The inorganic salts are chosen from those listed in claim 5, for example, sodium chloride, potassium chloride, aluminum sulfate, etc.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to include inorganic salts, particularly those taught by the '672 reference, in the composition of the '433 reference. ”

The Examiner further says in relation to the above statement, probably to reinforce the above position,

(1) “First, the '433 reference suggests a tangible advantage that could be gained from addition of such salts, namely, that the stability of the emulsion will increase. The artisan would thus find it obvious to add the salts and would expect a more stable emulsion. ” and

(2) “Second, the claims represent no more than the combination of elements known in the art, where each element serves its art-recognized, predictable function. The additional agent in the '433, the inorganic salts, are recognized as to act a stabilizer. Based on the disclosure, the inorganic salts appear to serve the same function in the instantly claimed invention; there is no evidence to indicate any unexpected result.”

#### Preliminary Matter

The opinion of the Examiner in the above (1) “the '433 reference suggests a tangible advantage that could be gained from addition of such salts, namely, that the stability of the emulsion will increase.” This is an opinion contrary to the fact and appears to be based on speculation. The '433 reference does not disclose any inorganic salt, and further, there is no suggestion therein on an effect that the stability of the emulsion is increased thereby.

Applicants disagree with these rejections for the following reasons:

Part 1 --

If the '433 reference is combined with the '672 reference, it is much beyond the range that a person skilled in the art expects, to incorporate the ester oil in such a high concentration, and moreover, if the '433 reference is combined with the '672 reference, it is an unexpected remarkable effect to a person skilled in the art that emulsion stability is maintained at an excellent level even when the ester oil is incorporated in such a high concentration. This is explained below.

(1) It is described in page 2, line 23 to page 3, line 10 of applicants' specification that ester oils have advantages in that they are excellent in miscibility with sebum, do not slide on the skin, have good affinity to the skin, do not impact a shine to the skin and so on, and further, they are excellent in air permeability and have less oil touch, and therefore, they are commonly used in cosmetics. But ester oils have disadvantages that they do not have satisfactory moisture-confining properties and their effect to improve rough skin or the like is poor, and further, when an ester oil is incorporated into a conventional water-in-oil emulsion, phase separation tends to occur, and the resulting emulsion has poor emulsion stability. The present invention has solved the above problems by use of an ester compound in combination with a water soluble inorganic salt.

Namely, in the invention according to new claim 20, by using together an ester compound, an ester oil, a surfactant and an oil other than ester oil, and further an water soluble inorganic salt, especially by using an ester compound, an ester oil and a water soluble inorganic salt together, the following advantages are made possible:

- (a) incorporating an ester oil in the oil phase in such a high compounding amount of 20 to 75 % by mass, and thereby, improving use touch (reduce of stickiness, improvement of rough skin),
- (b) enhancing moisture-confining properties, and
- (c) enhancing emulsion stability.

(2) The '433 reference discloses a sunscreen cosmetic as a water-in-oil emulsion preparation comprising an ester compound and an ultraviolet absorber (claim 1), and oils and surfactants are mentioned as optional ingredients (paragraph 20). However, the word "ester oil" is not mentioned in the '433 reference. "Ester oil" is not a word including all esters, and as

mentioned above, ester oils are esters having “advantages that they are excellent in miscibility with sebum, do not slide on the skin, have good affinity to the skin, are hard to shine the skin and so on, and further, they are excellent in air permeability and have less oil touch, and therefore, they are commonly used in cosmetics”. In the ‘672 reference, while it is true that the term “ester oil” is used in the ‘672 reference (paragraph 0039), no ester oil is used in the examples.

As mentioned above, an ester oil has various advantages, but since, as mentioned in the above (1), it has a disadvantage that when it is incorporated in a water-in-oil emulsion preparation, it lowers the emulsion stability of the preparation, there has been a problem that it is not possible to incorporate an ester oil in a sufficient amount to exert its effect sufficiently. Namely, for example, in the creams of paragraph [0030] and [0032] in JP-A-2000-86484 (‘484 document) and in the creams of paragraph [0027] and [0029] in JP-A-2001-187711 (‘711 document), submitted by the applicants, the compounding amounts of octyldodecyl myristate were as small as 1.0 % by mass (3.3 %, 3.1%, 3.1% and 2.8% by mass in terms of the compounding amounts in the oil phases, respectively; 1 to 6, 1 to 3, 1 to 7 and 1 to 4 respectively were assumed to belong to the oil phases). This is presumed to be attributed to restriction from emulsion stability as mentioned above.

In the invention according to new claim 20, it is made possible, by using together an ester compound, an ester oil, a surfactant and an oil other than ester oil, and further an water soluble inorganic salt, especially by using an ester compound, an ester oil and a water soluble inorganic salt together, to incorporate an ester oil stably in such a high compounding amount of 20 to 75 % by mass based on the oil phase, whereby use touch is improved. This effect is demonstrated in the Examples. Namely, for example, the compounding amounts of glycerol tri-2-ethylhexanoate as an ester oil in Examples 1 to 7 in the oil phases are calculated to be 25.3 % by mass, 25.5 % by mass, 25.3 % by mass, 42.1 % by mass, 25.3 % by mass, 25.3 % by mass and 25.3 % by mass, respectively (Table 2), and both emulsion stability and use touch are excellent (Table 5). On the other hand, in Comparative examples 1, 2, 4, 8, 9 and 10 where although no ester compound is used or only a too small amount of an ester compound is used, the ester oil is incorporated in a high compounding amount (the compounding amounts of glycerol tri-2-ethylhexanoate are calculated to be 25.0 % by mass, 25.3 % by mass, 25.3 % by mass, 25.3 % by mass, 25.3 % by mass and 31.9 % by mass, respectively), emulsion stability is inferior and

use touch is also inferior (Tables 3, 6 and 7), and further, also in Comparative example 3 where no water soluble inorganic salt is incorporated, emulsion stability is inferior.

(3) The '433 reference discloses that an ultraviolet absorber can be incorporated in a high compounding amount by addition of an ester compound, but does not disclose its effect on ester oils. Therefore, even if a person skilled in the art had thought of incorporating an ester oil and an inorganic salt described in the '672 reference into the sunscreen cosmetic described in the '433 reference, it is presumed that the compounding amount of the ester oil would have been a much smaller amount compared to that in the invention according to new claim 20.

In relation to this point, as apparent from the contrast between paragraph [0039] and paragraph [0042] of the '672 reference, from contrast between paragraph [0023] and paragraph [0025] of the '484 document and from contrast between paragraph [0020] and paragraph [0022] of the '711 reference, ester oils are separately explained from ultraviolet absorbers, and also in technical books, ester oils and ultraviolet absorbers are separately dealt with, and examples of ester oils do not include ultraviolet absorbers. As such technical books, there can, for example, be mentioned "Keshohin Handbook" (Cosmetics Handbook) published on November 1, 1996 by Nikko Chemicals Co., Ltd. and other two corporations, pages 48-66 (Esters) and pages 405-413 (Agents for protection from ultraviolet rays); "Koshohin Kagaku (Science of Perfumes and Cosmetics) 3rd Edition" written by Tateo TAMURA et al. and published on September 20, 1999 by FRAGRANCE JOURNAL LTD., pages 129-136 (Fatty acid esters) and pages 234-247(Ultraviolet absorbers); "Gendai Koshohin Gaku" (Knowledge of Modern Perfumes and Cosmetics) edited by Haruo KISHI and published on March 20, 1979 by Kodansha Co., Ltd., pages 41-42 (Esters) and pages 134-135 (Ultraviolet absorbers); "Kosumetorogii Nyumon" (Guide to Cosmetology) written by Mamoru SUZUKI and published on July 31, 1993 by Saiwai Shobo Co., Ltd., pages 160-161 (Synthetic esters) and page 190 (Ultraviolet absorbers); and "Shin Keshohin Gaku" (Knowledge of New Cosmetics) edited by Tetsusaku IKEDA and published on January 10, 1978 by Nanzando CO., Ltd., pages 135-136 (Esters) and 150-152 (Ultraviolet absorbers).

In order to formally make these documents of record and reflect the fact that they were considered during examination submitted herewith is an Information Disclosure Statement formally listing these documents.

Therefore, it cannot be said that the effect on ultraviolet absorbers in the '433 reference gives a person skilled in the art any suggestion about similar effects on ester oils. With respect to this, there is a description "an ultraviolet absorber as an ester oil" in page 3, paragraph 2 of the English text, but this is merely a personal comment of the inventors, and the description cannot be amplified as recognition of a person skilled in the art. Namely, it should be determined in accordance with contemporary knowledge of a person skilled in the art prior to the filing date/priority date whether ultraviolet absorbers belong to ester oils or not, and it should not be decided in accordance with a personal comment of the inventors.

(4) As apparent from the above, even if the '433 reference is combined with the '672 reference, it is much beyond a range expected by a person skilled in the art, to incorporate an ester oil in such a high concentration, namely in an amount of 20 to 75 % by mass based on the mass of the oil phase (the total mass of the ester compound, the ester oil, the surfactant and the oil other than ester oil) as in new claim 20, and moreover, even if the '433 reference is combined with the '672 reference, it is a remarkable effect unexpected by a person skilled in the art that even when an ester oil is incorporated in such a high concentration, excellent emulsion stability can be maintained.

#### Part 2--

There is no suggestion/motivation to combine an ester compound with an ester oil in the '433 reference nor in the '672 reference, and further, there is no suggestion/motivation on use a ratio of both in either reference, and in view of this, a person skilled in the art would not have envisioned the invention according to new claim 20 (hereinafter, sometimes referred to the present invention). This is explained below.

(1) Among ingredients used in the present invention, those mentioned in the '433 reference are ester compounds and surfactants (paragraph 0020), and further, "oils" are mentioned (paragraph 0020) and in Table 2, liquid paraffin, squalane and octamethylcyclotetrasiloxane (these are classified into the oil other than ester oil in the present invention) are used. Ester oils are not mentioned in the '433 reference (as to the reality that a person skilled in the art would never regard ultraviolet absorbers as belonging to ester oils, as thoroughly explained above). Among the ingredients used in the present invention, ones mentioned in the '672 reference are inorganic salts, and further, "ester oils" are mentioned

(paragraph 0039). Therefore, all ingredients used in the present invention can be found from both references.

However, in the '433 reference, ultraviolet absorbers are also an indispensable ingredient, and besides surfactants and oils, various additives such as wetting agents, antioxidants, humectants and thickeners can be used as optional ingredients (paragraph 0020), and also in the '672 reference, "(A) a composite obtained by mixing an amphoteric surfactant and/or a semipolar surfactant with a higher fatty acid" is also an indispensable ingredient (claim 1), and besides ester oils, waxes, hydrocarbon oils, fatty acids, silicone oils, etc. are mentioned as optional oils, and further, as other optional ingredients, water soluble polyhydric alcohols, humectants, ultraviolet absorbers, resins, protein hydrolyzates, etc. can be used (paragraph 0042).

(2) First of all, it is a question -- would a person skilled in the art have thought of combining an ester compound with an ester oil among these various possible ingredients. There is no mention about ester oils in the '433 reference, and in the '672 reference, ester oils are merely mentioned as one possible ingredient among various oils and other ingredients. There is no suggestion or motivation in either of the references to separate an ester oil from other oils and other ingredients and combine it with an ester compound.

(3) In page 10, paragraph 2 of applicants' specification, there is the following: "The use ratio of the ester compound to the ester oil in the oil phase of the water-in-oil emulsion preparation for external use on the skin of the invention is preferably 1:99 to 95:5..... When the use ratio of the ester compound is less than 1:99, moisture-confining properties generally tend to be inadequate" (in new claim 20, the use ratio of the ester compound to the ester oil is calculated to be about 1.32:98.68 to 50:50), there is no suggestion/motivation in either of the references to use the ester compound and the ester oil in such a mutual ratio. In this connection, the above matter is demonstrated in the Examples. Namely, the use ratios of the ester compound to the ester oil in Examples 1-7 are 25:75 in Examples 1, 2, 5, 6 and 7, about 11.8:88.2 in Example 3 and about 16.7:83.3 in Example 4 (Table 2), and moisture-confining properties in each example are excellent (Table 5), whereas in Comparative example 4, the use ratio is about 0.33:99.67 and out of the above range (Table 3), and moisture-confining properties are inferior (Table 6).

Part 3—

The effect of the invention according to new claim 20 (the present invention) is that not only excellent emulsion stability but excellent use touch and excellent moisture-confining properties are attained at the same time. If the '433 reference and the '672 reference are combined, all the ingredients used in the invention according to new claim 20 may be carefully selected and arranged, but moisture-confining properties are not recognized in any of the references, and as a matter of course, a means to envision moisture-confining properties is not suggested therein at all. Therefore, even if a person skilled in the art had conceived of an idea to combine the '433 reference with the '672 reference, he would have never reached the present invention capable of realizing excellent moisture-confining properties. This is explained below.

(1) Although two Office Actions have been issued, no mention is made of moisture-confining properties as one of the characteristics of the present invention. Especially, although the applicants had argued in their Remarks against the first Office Action that excellent moisture-confining properties are an unexpected remarkable effect of the present invention, no mention was made in the second Office Action on the effect of moisture-confining properties. Applicants postulate that this is because the Examiner thinks that when the '433 reference is combined with the '672 reference, the effect of moisture-confining properties follows.

However, if a question of whether it can simply be said that combination of the '433 reference with the '672 reference is accompanied by a display of the effect of moisture-confining properties is made, the answer is no. It is necessary to exhibit the effect of moisture-confining properties to use the ester compound so that the proportion of ester compound in the use ratio of the ester compound to the ester oil could be equal to or more than 1:99. Since no ester oil is mentioned in the '433 reference, and in the '672 reference, although ester oils are mentioned, their use amount is not mentioned, there is no mention in either of the references to suggest the use ratio between ester compounds and ester oils. Therefore, even if both are combined without recognition of the effect of moisture-confining properties, it can hardly be said that the above use ratio is reached

From the above three points, it is believed that the invention according to new claim 20 is not subject matter which could have readily been conceived by a person skilled in the art over the '433 reference in view of the '672 reference, and it is patentable. New claims 21 to 27 are



KACHI, H. et al.  
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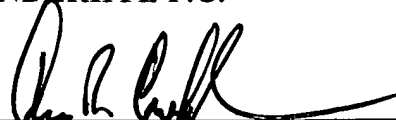
claims subordinate to new claim 20, and derive patentability from the independent claims; *see* MPEP §2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Reconsideration and favorable action are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

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